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SIMMONSFIRM.COM
(800) 479-9533

December 7, 2022

VIA ECF
Hon. Valerie Figueredo
Daniel Patrick Moynihan U.S. Courthouse
500 Pearl Street
New York, NY 10007-1312

Re: *Gref v. Am. Int'l Indus.*, et al., 20-cv-05589

Dear Judge Figueredo:

Following the deadline for Plaintiff's opposition to Defendants' Motion to Compel the Continuation of the deposition of Plaintiff's Expert Dr. Moline, two defense experts provided testimony that directly contradicts the Defendants' argument that they are entitled to discover the identities of subjects of the peer-reviewed article Dr. Moline co-authored, entitled "Mesothelioma Associated With the Use of Cosmetic Talc." Given that this article is the primary focus of Defendants' Motion, Plaintiff respectfully requests the Court permit him to supplement his opposition with the pertinent testimony that undermines Defendants' claim.

On November 23, 2022, Dr. Kenneth A. Mundt, an epidemiologist retained by Defendants American International Industries ("AII"), Whittaker Clark & Daniels, Inc. ("WCD"), and Shulton, Inc. ("Shulton"), testified about the procedures he followed to maintain the confidentiality of human research subjects when working on an epidemiological study regarding occupational exposures to hexavalent chromium, a carcinogenic toxin. *See* Excerpts of Dr. Mundt Dep. Vol II, dated Nov. 23, 2022, attached as **Exhibit 1** at 142:20-143:16 (identifying the draft of the study and confirming Dr. Mundt founded Applied Epidemiology, Inc.), 144:22-145:6 (confirming he was responsible for the draft and its contents), 179:3-181:24 (discussing procedures to maintain confidentiality of subjects); *See* Collaborative Cohort Mortality Study of Five Chromate Production Facilities, 1958-1998 (Draft Protocol, dated Apr. 23, 1999), attached as **Exhibit 2** at 4. A draft of this study included an entire section on the "Protection of Human Subjects." **Exhibit 2** at 4. As confirmed at his deposition, Dr. Mundt followed "standard epidemiological procedures" to protect the confidentiality of the human subjects and "no results [were] presented other than in aggregate form, and no individual identity can be discerned." **Exhibit 2** at 4. Specifically, like Dr. Moline's study, Dr. Mundt completed his study with the permission of an Institutional Review Board that was registered with the federal government and responsible for "protecting human subjects." **Exhibit 1** at 180:12-181:6. Regarding specific rules and procedures, Dr. Mundt referenced "the human protections section of the Health and Human Services. There was extensive protocols, registrations, training that was involved." *Id*. at 181:13-16.

On December 2, 2022, Dr. Kerry Robin Carder, a pediatric dermatologist retained by Defendant American International Industries ("AII"), testified in connection with her personal experience researching and publishing peer-reviewed literature involving human research subjects

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that the identities of such subjects is protected information under HIPAA, as well as other laws and ethical rules.[1]

> QUESTION: Have you ever revealed the identities of any of the studies of human subjects reported such as in what we're looking at here, Exhibit 5?
>
> [Objection omitted]
>
> ANSWER: I'm not sure what you mean by revealing identities. Patient identities or --
>
> QUESTION: Patient identities, that's right.
>
> ANSWER: No.
>
> QUESTION: Are there rules governing or protecting the identification of patient identities such as the infants in this article?
>
> [Objection omitted]
>
> ANSWER: Yes.
>
> […]
>
> QUESTION: Okay. And does HIPAA govern the protection of their identities?
>
> ANSWER: HIPAA and there are certain laws in place for those who are doing studies, but these were not studies, these were case reports.
>
> So, yes, you either have to have the permission from the family if you do have, say, an identifiable photograph or – yes.
>
> QUESTION: Okay. And then going back to my former question, are there any ethical guidelines within the medical profession that would prevent or advise against the identification of any of the patients in those published studies on those case reports?
>
> [Objection omitted]
>
> ANSWER: There – just like HIPAA guidelines, yes, there are guidelines in place […]
>
> [Objection Omitted]

[1] Notably, Dr. Carder provided this testimony despite AII's counsel raising baseless objections and instructing her not to answer Plaintiff's questions. Dr. Carder clearly has personal knowledge and expertise that is relevant to understanding the privileged and confidential nature of human research subjects featured in peer-reviewed medical literature.

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> QUESTION: And just so I understand your answer, Dr. Carder, are you referring to something in addition to HIPAA or are you referring specifically to HIPAA?
>
> ANSWER: HIPAA is part of it, but there are similar guidelines for those who are doing studies.
>
> QUESTION: And what are those guidelines?
>
> ANSWER: Just that you protect the patient identity.

See Excerpts of Dep. of Dr. Carder, dated Dec. 2, 2022, attached as **Exhibit 3** at 54:22-61:19.

The foregoing testimony, along with the testimony of other defense experts cited in Plaintiff's opposition papers, confirm that, as maintained by Northwell Health and Dr. Moline, the identities of the human research subjects involved in Dr. Moline's 2020 peer-reviewed article are confidential and protected information that is immune from discovery. For this reason and the many others set forth in Plaintiff's opposition, Defendants' Motion to Continue the Deposition of Dr. Moline must be denied in its entirety.

Respectfully submitted,

James M. Kramer